DETAILED ACTION

Applicant's election without traverse of Group I (claims 1-7, 10-12, and 15-19) and election of a specific compound N-[3-(4-{[6-({(2R)-2-[3-(formylamino)-4-hydroxyphenyl]-2-hydroxyethyl}amino)hexyl]oxy}butyl)phenyl]urea, in the reply filed on July 16, 2008 is acknowledged. Claims 1-7, 10-12, and 15-17 read on both the elected invention (group I) and the elected species, and thus claims 1-7, 10-12, and 15-17 are present for examination.

Applicant submitted and information disclosure statement (IDS) on April 29, 2005. Applicant cited 3 foreign patent documents but did not provide them, and as such they were not considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 10-12, and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has claimed compounds of formula I or "a salt, solvate, or physiologically functional derivative thereof". Applicant has not shown what a solvate or physiologically functional derivative would constitute in regards to the elected species. Furthermore, since the compound is free of the art, little is know about the compound and how it acts and therefore it would extremely difficult to predict what type of compounds would be physiologically functional derivatives. Also given the lack of information in the prior art about the elected species, forming solvates of the compound would also not be straightforward and neither derivative would be easily determined. One of skill in the art would not be able to determine which compounds are encompassed by the terms "solvate" and "physiologically functional derivative" and thus claims 1-7, 10-12, and 15-17 lack written description of the invention.

Claims 1-7, 10-12, and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has claimed compounds and pharmaceutical compositions comprising the elected species, N-[3-(4-{[6-({(2R)-2-[3-(formylamino)-4-hydroxyphenyl]-2-hydroxyethyl}amino)hexyl]oxy}butyl)phenyl]urea. However, applicant has not shown how to make their invention such that one of skill in the art at the time of the invention

would make the compound elected. Applicant describes the synthesis of the elected compound on pages 38-39, however applicant starts with a complicated starting material (page 38, line 24) which does not appear to be commercially available. Applicant has pointed towards a reference WO 0276933, however upon examination of that document, the starting material claimed was not found, nor was the procedure for how to make such a starting material. Thus since one of skill in the art would not know how to make the starting material, they could not make the invention as claimed.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The quantity of experimentation necessary would be large (1) due to the lack of direction provided (2) and the fact that the examples start with a compound that itself is not well known in the art and its synthesis is unknown (3). The nature of the invention is organic synthesis (4) which is complicated and unpredictable (7). The state of the prior art is such that the elected species is not known and the starting material is possibly

unknown or at least not commonly known (5). The relative skill of those in the art is high (6) however the breadth of the claims is also large due to applicant's claims of solvates and derivatives of the elected species (8).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has claimed a pharmaceutical formulation with compounds of formula I, and "one or more therapeutic ingredients". It is unclear what applicant considers a therapeutic ingredient, it would essentially be any drug or compound that might have a benefit, even those such as excipients which have a benefit in that they make the composition more effective or tolerable, etc. Thus applicant appears to be claiming everything, which is indefinite, and applicant has failed to point out and **distinctly** claim the subject matter which applicant regards as the invention.

Conclusion

No claims are allowed.

The elected species is free of the prior art.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
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